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Subject: Environmental Defense Comments on Aldehydes, C4, self condensation products, high boiling point fraction (solvent C) CAS#68990-21-6

(Submitted via Internet 1/28/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciarg@msn.com and deyo@eastman.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Aldehydes, C4, self condensation products, high boiling point fraction (solvent C).

This chemical mixture, Aldehydes, C4, Self-Condensation Products, High Boiling Fraction, termed Solvent C, is sponsored by Eastman Kodak. According to the sponsor it is produced in a closed system, consists of a mixture of 10 major chemicals and is used primarily on site as a fuel. Whereas from these uses it would appear that public and environmental exposure are minimal, transport of Solvent C and its use in home heating oil does provide some opportunity for public and environmental exposure. Solvent C itself has apparently not been the subject of toxicological testing.

The sponsor asserts that its obligation to the HPV program for Solvent C has been completed by this submission. We do not agree with that assertion for the reasons given below:

1. The sponsor states that 7 of the 10 chemicals which comprise Solvent C have been or will be evaluated through the OECD, ICCA SIDS or US HPV programs. However, for only one chemical (neopentyl glycol) has such an assessment been completed and published; another of the 7 is included in a separate test plan and robust summary submitted under the US HPV Program; OECD SIDS assessments for two others are apparently complete but have yet to be published; three others are in an early stage of the OECD SIDS program and the timing of their completion is uncertain. Therefore, information for 5 of the substances is incomplete or unavailable, and hence inadequate at this time for satisfying HPV screening level purposes. When the data become available for those substances we will be pleased to provide our evaluations, but at this point it cannot be claimed that the sponsor has fulfilled requirements of the HPV program.

2. For the other 3 of the 10 chemicals, despite an indication that considerable data exist for them or their metabolites, none of these data have been provided in the form of robust summaries; merely asserting the existence of such data and providing references does not fulfill the requirements of the HPV program.

3. 2-Ethyl-1,3-hexanediol is a constituent of Solvent C. It was once used as an insect repellent and it may still be used in cosmetics and several industrial applications. The sponsor claims that HPV requirements are met by existing published data. However, these data are obtained by cutaneous exposures. This route of exposure is appropriate for the use of 2-ethyl-1,3-hexanediol as an insect repellent but perhaps not for some of its industrial uses. The sponsor provides no discussion of this point.

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4. The sponsor states that another chemical in Solvent C, butyl butyrate, is expected to be metabolized to butyric acid and butanol, both of which are covered under the ICCA SIDS Program. However, no scientific data are provided on butyl butyrate metabolism in the test plan or robust summaries and the assessments for the ICCA SIDS assessments for butyric acid and butanol have not yet been released. Therefore it is premature to state that the HPV requirements for butyl butyrate have been met.

5. This HPV submission is for a chemical mixture (Solvent C), not for its individual constituents. However, no data are provided for the mixture itself. We know from numerous cases in the scientific literature that mixtures can be much more or less toxic than would be predicted by the sum of the individual constituents. Therefore, we recommend that the sponsor conduct repeat dose, in vitro genetic toxicity and ecotoxicity studies on Solvent C. The sponsor contends that this is not feasible because the composition of Solvent C is variable. But the data provided in Table 1 of the robust summaries indicate that the range of concentrations is not large. For example the range for the di-2-ethylhexyl ether is 25-35% and for butyl butyrate is 8-16% and the rest of the constituents have similar limited variability in concentration ranges. We recommend that the sponsor use the midpoint concentration range for each of the constituents in conducting the studies we recommend.

Thank you for this opportunity to comment.

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